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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,261	02/18/2004	Steven Rubin	102927-200	3156

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WIGGIN AND DANA LLP
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EXAMINER

ROGERS, JUNE MARIE

ART UNIT	PAPER NUMBER
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4173

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10/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,261

Applicant(s)

RUBIN, STEVEN

Examiner

Juné M. Rogers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1 and 4-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Due to claim amendments files on 9/17/2007, the restriction requirement has been modified as below and the previous restriction mailed on 7/24/2007 is vacated.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 4-26 drawn to an acne treatment regimen containing:
 - a. a cleaning composition comprising an anti-acne active and one of more cleaners
 - b. an acne spot treatment composition comprising an anti-active ingredient
 - c. a hydrating day cream composition comprising an anti-active ingredient and a combination of farnesol and sodium hyaluronate
 - d. an acne night cream composition comprising an anti-acne active and a combination of farnesol and sodium hyaluronate classified in class 514, subclass 859
- II. Claims 27 drawn to a kit comprising a container of the (a) acne cleanser composition comprising an anti-acne active (b) a container of the acne spot treatment composition comprising an anti-active ingredient (c) a container of the hydrating day cream composition comprising an anti-

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active ingredient and a combination of farnesol and sodium hyaluronate
an anti-acne active (d) a container of the acne night cream composition
comprising an anti-acne active and a combination of farnesol and sodium
hyaluronate, classified in class 514, subclass 859

- III. Claims 28 drawn to a composition comprising an anti-acne active ingredient and a combination of farnesol and sodium hyaluronate, classified in class 514, subclass 859.
- IV. Claims 29-51, drawn to an acne treatment regimen containing:
 - a. a cleaning composition comprising an salicylic acid and one or more cleaners
 - b. an acne spot treatment composition comprising salicylic acid
 - c. a hydrating day cream composition comprising salicylic acid and a combination of farnesol and sodium hyaluronate
 - d. an acne night cream composition comprising salicylic acid and a combination of farnesol and sodium hyaluronate classified in class 514, subclass 159.
- V. Claim 52, drawn to a kit comprising a container of the (a) acne cleanser composition comprising salicylic acid (b) a container of the acne spot treatment composition comprising salicylic acid (c) a container of the hydrating day cream composition comprising salicylic acid and a combination of farnesol and sodium hyaluronate an anti-acne active (d) a container of the acne night cream composition comprising salicylic acid

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and a combination of farnesol and sodium, classified in class 514, subclass 159.

- VI Claim 53, drawn to a composition comprising salicylic acid and a combination of farnesol and sodium hyaluronate, classified in class 514, subclass 159.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the containers and their contents can be used in a treatment regimen for psoriasis.

Inventions I, IV and III, VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, product can be administered orally.

Inventions I and IV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can

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have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the invention of Group I does not require the presence of salicylic acid therefore the invention of Group I has a materially different design than the invention of Group IV.

Inventions III and IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the invention of Group III does not require the presence of salicylic acid therefore the invention of Group IV has a materially different design than the Invention of Group IV.

Restriction Proper

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

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(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoinder Notice

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

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§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specie Election

This application contains claims directed to the following patentably distinct species:

anti-acne active, enumerated in claims 1, 4-7

cleaners, enumerated in claims 8-13, 33-38

further comprising ingredients enumerated in claims 14, 21, 26, 39, 41, 46, and

51

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. **Specifically**, If Applicant elects the invention of Groups I or II, Applicant is **required** to elect (1) the presence of absence of any further comprising

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ingredients. If applicant elects the presence of further comprising ingredients; Applicant is **required** to elect a single specific further comprising ingredient for

- (a) the acne cleaner composition
- (b) the acne spot treatment composition
- (c) the hydrating day cream composition
- (d) the acne night cream composition

(2) Applicant is to elect a single specific specie of anti-acne active; (3) Applicant is to elect a single specific specie of cleaner or combination of cleaners.

If Applicant elects the Invention of Group III, applicant is **required** to elect a single specie of anti-acne active.

If Applicant elects the Inventions of Groups IV or V Applicant is **required** to elect (1) the presence of absence of any further comprising ingredients. If applicant elects the presence of further comprising ingredients; Applicant is **required** to elect a single specific further comprising ingredient for

- (a) the acne cleaner composition
- (b) the acne spot treatment composition
- (c) the hydrating day cream composition
- (d) the acne night cream composition

(2) Applicant is to elect a single specific specie of cleaner or combination of cleaners.

Currently, claims 1,4- 28,33-41,46, and 51-52 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of

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search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

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prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

Due to the complicated nature of the restriction, the election requirement is being made via written correspondence in lieu of a telephone interview.

Contact Information

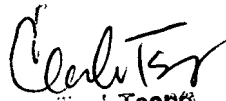
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juné M. Rogers whose telephone number is 571-270-3497. The examiner can normally be reached on M-T 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Juné M. Rogers


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